IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al. v. AMERICAN HOME PRODUCTS CORPORATION	)	CIVIL ACTION NO. 99-20593
	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9352

Bartle, J. September 13, 2014

Elizabeth Nielson ("Ms. Nielson" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits") and, if so, whether she met her burden of proving that her claim was not based, in whole or in part, on any intentional material misrepresentation of fact.[3]

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Dean Nielson, Ms. Nielson's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In November, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Richard Callihan, M.D. Dr. Callihan is no stranger to this litigation. According to the Trust, he has signed at least 1,040 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated August 8, 2002, Dr. Callihan attested in Part II of claimant's Green Form that Ms. Nielson suffered from

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3. (...continued)
(Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

moderate mitral regurgitation and an abnormal left atrial dimension.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $522,266.[5]

In the report of claimant's echocardiogram, the reviewing cardiologist, W. Marcus Brann M.D., F.A.C.C., F.A.C.P., stated that Ms. Nielson had moderate mitral regurgitation, which he measured at 27%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Brann also noted that Ms. Nielson suffered from "mild left atrial enlargement," measuring 56 mm and 43 mm in the supero-inferior systolic dimension and antero-posterior systolic dimension, respectively. The Settlement Agreement defines an abnormal atrial dimension as a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view or a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view. See id. at § IV.B.2.c.(2)(b)ii).

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4. Dr. Callihan also attested that claimant suffered from moderate aortic regurgitation. This condition is not at issue in this claim.

5. Under the Settlement Agreement, an eligible class member is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension is one of the complicating factors necessary for a Level II claim.

In February, 2004, the Trust forwarded the claim for review by Jeremy I. Nadelmann, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Nadelmann concluded that there was a reasonable medical basis for Dr. Callihan's findings of moderate mitral regurgitation and an abnormal left atrial dimension.

Based on Dr. Nadelmann's findings, the Trust issued a post-audit determination letter awarding Ms. Nielson Matrix Compensation Benefits. Before the Trust paid Ms. Nielson's claim, we imposed a stay on the processing of claims pending implementation of the Seventh Amendment to the Settlement Agreement. See Pretrial Order ("PTO") No. 3511 (May 10, 2004). Prior to the entry of the stay, the Trust identified 968 Matrix claims that had passed audit as payable, which were designated as "Pre-Stay Payable Post-Audit Determination Letter ('PADL') Claims." Pursuant to Paragraph 5 of PTO No. 3883, the Trust was ordered to separate the Pre-Stay PADL Claims into three categories. Of the 968 Pre-Stay Payable PADL Claims, the Trust alleged that 580 claims, including Ms. Nielson's, contained intentional material misrepresentations of fact. These 580 claims are commonly referred to as "5(a) claims." See PTO No. 3883, at ¶ 5 (Aug. 26, 2004).

Following the end of the stay, we ordered the Trust to review the 580 claims designated as 5(a) claims and issue new post-audit determinations, which claimants could contest. See PTO No. 5625 (Aug. 24, 2005). On November 22, 2006, prior to the

Trust's review of Ms. Nielson's claim, this court approved Court Approved Procedure ("CAP") No. 13, which provided 5(a) claimants with the option either to submit their claims to a binding medical review by a participating physician or to opt-out of CAP No. 13. See PTO No. 6707 (Nov. 22, 2006). Ms. Nielson elected to opt-out of CAP No. 13.

The Trust therefore undertook to determine whether there were any intentional material misrepresentations of fact made in connection with Ms. Nielson's claim.[6] As part of this review, the Trust engaged Joseph Kisslo, M.D., to review the integrity of the echocardiogram system used during the performance of echocardiographic studies and the resulting interpretation submitted in support of Ms. Nielson's claim. As stated in his January 26, 2007 declaration, Dr. Kisslo determined, in pertinent part:

> In Ms. Nielson's study, the use of high color gain, high image gain, color persistence, decreased low velocity reject and color pixels dominant over anatomy, the selection and planimetry of backflow, and the overmeasurement of the mitral and aortic "jets," as well as the overmeasurement of the left atrial dimension are the result of deliberate choices and conduct engaged in by the sonographer performing this study and at a minimum, acquiesced in by the Attesting Physician. Each of these manipulations

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6. In November, 2004, the Trust had provided Ms. Nielson with an "Expert Report" signed by Dr. Kisslo pursuant to Paragraph 11 of PTO No. 3883. In that report, Dr. Kisslo opined that "[t]he appearance of a regurgitant jet was manufactured through excessive color gain, color pixels dominant over anatomy, color persistence, two-dimensional gain and image persistence, the incorporation of backflow and other non-regurgitant flow in the measurement, and the drawing of a jet outside any color boundary."

> exaggerated or created the appearance of regurgitation, jet duration or a complicating factor.... Ms. Nielson has only trivial mitral regurgitation[7] ....

Accordingly, not withstanding Dr. Nadelmann's findings at audit, the Trust issued a post-audit determination denying Ms. Nielson's claim based on its conclusion that there was substantial evidence of intentional material misrepresentations of fact in connection with the claim. Pursuant to the Rules for Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[8] In contest, claimant argued that the results of Dr. Nadelmann's audit, who claimant described as "the only impartial unbiased cardiologist to review [the] echocardiogram tape (besides Ms. Nielson's attesting cardiologist)," supported her claim. Ms. Nielson also attached a September 8, 2005 letter from Class Counsel to the Trust[9] and a

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7. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace, trivial, or physiologic regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular place or <+ 5% RJA/LAA."

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Nielson's claim.

9. In this letter, Class Counsel argued, among other things, that the Trust could not deny payment on any claim in which a post-audit determination letter had been sent unless it found that the claim was based on a fraudulent echocardiogram and that the Trust could not rely on the reports of Dr. Kisslo to determine whether a claim in which a post-audit determination

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motion filed on behalf of a number of other claimants to enforce PTO No. 5632 or to set aside PTO No. 5632 and to compel production of certain Trust documents,[10] each of which she contended established that Dr. Kisslo was neither reliable nor credible. Claimant further asserted that Dr. Kisslo's findings were "nothing more than unsubstantiated assertions." Finally, Ms. Nielson argued that the Trust failed to meet the legal requirements for a claim of intentional material misrepresentation of fact.

The Trust then issued a final post-audit determination, again denying Ms. Nielson's claim. The Trust argued that Dr. Nadelmann's audit results did not support Ms. Nielson's claim because Dr. Nadelmann, unlike the Consensus Expert Panel, was not trained to detect the manipulations used by claimant's sonographer. The Trust also asserted that claimant failed to establish a reasonable medical basis for her claim because she "[did] not identify any alleged errors made by Dr. Kisslo" or "address in any way the specific content of his Declaration." In addition, the Trust contended that Ms. Nielson's reliance on the September 8, 2005 letter of Class Counsel was misplaced.

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9. (...continued)
letter had been sent was fraudulent. The issues raised in Class Counsel's letter also were the subject of a motion filed by Class Counsel and joined by a number of firms representing various Class Members. Class Counsel and all but one firm subsequently withdrew the motion after the adoption of certain Court Approved Procedures. We denied the motion of the remaining firm following briefing and argument. See PTO No. 6099 (Mar. 31, 2006).

10. We subsequently denied the motion. See Mem. in Supp. of PTO No. 9114 at 6 n.8 (July 23, 2013).

Ms. Nielson disputed the Trust's final determination and requested that her claim proceed through the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for an Order to show cause why Ms. Nielson's claim should be paid. On June 12, 2007, we issued an Order to show cause and referred this matter to the Special Master for further proceedings. See PTO No. 7253 (June 12, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master, which incorporated by reference the materials she submitted in contest. The Trust did not reply. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[11] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report

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11. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for her claim.[12] Where the Trust's post-audit determination finds intentional material misrepresentations of fact, the claimant has the burden of proving that all representations of material fact in connection with the claim are true. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue either because of an intentional material misrepresentation of fact or some other valid reason, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers with no intentional material misrepresentation of fact made in connection with the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that it was not conducted in a manner consistent with medical standards. Specifically Dr. Vigilante observed:

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12. Given our resolution with respect claimant's level of mitral regurgitation, we need not determine whether there is a reasonable medical basis for finding that she suffered from an abnormal left atrial dimension.

> All of the usual echocardiographic views were obtained. However, the images were not conducted in a manner consistent with medical standards. There was definite excessive two dimensional echo gain with distortion of cardiac structures and sparkling in the tissues. There was excessive color gain with color artifact noted within the tissue. The low velocity reject setting was 2.6 cm per second. The pulse repetition frequency was 4,000 Hz. Persistence was also noted during color flow evaluation of the regurgitant jets. There was no apparent imaging issue that would cause the sonographer to use a low velocity reject setting of 2.6 cm per second.

Despite these deficiencies, Dr. Vigilante noted that he was able to evaluate claimant's echocardiogram and determined that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Dr. Vigilante explained, in pertinent part:

> Only mild centrally located mitral regurgitation was noted in the parasternal long axis view. Color flow evaluation of the mitral regurgitation jet occurred in the apical two chamber and apical four chamber views. There was significant artifact noted. Very mild mitral regurgitation was noted in the apical two chamber view with a RJA/LAA ratio of less than 10%. The mitral regurgitation jet was most impressively noted in the apical four chamber view. However, most of the color flow abnormality was backflow and not true mitral regurgitation, as this artifact was not seen throughout systole. Only a small mitral regurgitation jet was found throughout systole. I digitized all of the cardiac cycles in the apical two chamber and apical four chamber views during which color flow was being evaluated. I was able to accurately measure the LAA. I found the LAA to be 18.1 cm2. I was able to accurately evaluate the RJA in the mid portion of systole devoid of backflow artifact. The RJA was less than 2.3 cm2 in the majority of cardiac cycles. The largest RJA was found to be less than 3.2 cm2 in the

> apical four chamber view. Therefore, the largest RJA/LAA ratio was less than 18%. The majority of RJA/LAA ratios were less than 13% in the apical four chamber view. Therefore, I determined that the echocardiogram of August 8, 2002 demonstrated mild mitral regurgitation. The RJA/LAA ratio never approached 20%. The sonographer made two measurements of the supposed RJA. These measurements were 5.47 cm2 and 5.59 cm2. These measurements were grossly inaccurate and reflected backflow and not true mitral regurgitation. The sonographer measured the LAA to be 18.05 cm2. This measurement was accurate.

After reviewing the entire show cause record, we find claimant has not established a reasonable medical basis for the attesting physician's finding that Ms. Nielson had moderate mitral regurgitation. In reaching this determination, we are required to apply the standards delineated in the Settlement Agreement and Audit Rules. In the context of these two documents, we previously have explained that conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See Mem. in Supp. of PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Kisslo found that claimant's sonographer improperly "selected, traced, and measured a supposed regurgitant 'jet' that consist[ed] of backflow, entrainment, and areas outside of the jet boundary rather than true high velocity sustained regurgitant flow." Similarly, Dr. Vigilante determined that "most of the color flow abnormality [in the apical four chamber view] was backflow and not true mitral regurgitation." Dr. Kisslo and Dr. Vigilante also found that the echocardiogram of attestation was not conducted in a manner consistent with medical standards because, among other things, the echocardiogram settings included increased color and image gain, persistence, and decreased low velocity reject.

Notwithstanding these deficiencies, Dr. Kisslo determined that claimant's echocardiogram demonstrated only trivial mitral regurgitation. In addition, Dr. Vigilante concluded, after a thorough review, that there was no reasonable medical basis for the attesting physician's representation that Ms. Nielson had moderate mitral regurgitation. Dr. Vigilante explained that "the largest RJA/LAA ratio was less than 18%" and that "[t]he majority of RJA/LAA ratios were less than 13%."

Claimant offers little substantive challenge to these specific findings aside from contending that Dr. Kisslo was biased in his review and lacked the requisite independence to validate his findings. Notably, Ms. Nielson makes no such contention against Dr. Vigilante, who reached similar conclusions during a separate review. Without identifying some specific

error by the Trust's expert and the Technical Advisor, claimant cannot meet her burden of proof in establishing that her claim is payable.

We conclude, based on our review of the entire record, that there is no reasonable medical basis for Dr. Callihan's representation that claimant had moderate mitral regurgitation. Thus, we need not determine whether there was, in fact, any intentional material misrepresentation of fact in connection with Ms. Nielson's claim.[13]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Nielson's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

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13. As we previously have stated, "[s]imply because an undeserving claim has slipped through the cracks so far is no reason for this court to put its imprimatur on a procedure which may allow it to be paid." Mem. in Supp. of PTO No. 5625, at 6-7 (Aug. 24, 2005). In this same vein, we will not ignore the findings of other cardiologists simply because a claim has previously passed audit.